

From the:
INTERNATIONAL SEARCHING AUTHORITY

To:

A. J. Park
PO Box 949
Wellington
NEW ZEALAND

RECEIVED

17 NOV 2004

AJ PARK

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

| | | | |
|---|--|--|------------|
| | | Date of mailing (day/month/year) | 5 NOV 2004 |
| Applicant's or agent's file reference 504319 NJC | | FOR FURTHER ACTION See paragraph 2 below | |
| International application No. PCT/NZ2004/000194 | International filing date (day/month/year) 20 August 2004 | Priority date (day/month/year) 3 September 2003 | |
| International Patent Classification (IPC) or both national classification and IPC Int. Cl. 7 A61M 16/06 A62B 18/02 | | | |
| Applicant FISHER & PAYKEL HEALTHCARE LIMITED (ET AL.) | | | |

1. This opinion contains indications relating to the following items:

| | | |
|-------------------------------------|--------------|--|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the opinion |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input checked="" type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability: citations and explanations supporting such statement |
| <input checked="" type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

| | |
|---|---|
| Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6283 3929 | Authorized Officer MATTHEW FORWARD Telephone No. (02) 6283 2606 |
|---|---|

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Box No. I Basis of the opinion

With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

This opinion has been established on the basis of a translation from the original language into the following language, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

a sequence listing
 table(s) related to the sequence listing

b. format of material

in written format
 in computer readable form

c. time of filing/furnishing

contained in the international application as filed.
 filed together with the international application in computer readable form.
 furnished subsequently to this Authority for the purposes of search.

3. In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

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Box No. IV Lack of unity of invention

1. In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has:

paid additional fees
 paid additional fees under protest
 not paid additional fees.

2. This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is:

complied with
 not complied with for the following reasons:

The claims do not relate to one invention only (or to a group of inventions so linked as to form a single general inventive concept). In assessing whether there is more than one invention claimed, I have given consideration to those features which can be considered to be "special technical features". These are features that potentially distinguish the claimed combination of features from the prior art. Where different claims have different special technical features they define different inventions. I have found claims having different special technical features as follows:

(1) Claims 1-12. It is considered that "one narrow outlet vent" comprises a first special technical feature.
 (2) Claims 13. It is considered that "hollow body and a cushion where said cushion extends below said user's chin" comprises a second special technical feature.

Since these groups of claims do not share any of the special technical features identified, a technical relationship between the inventions does not exist. Accordingly the claims do not relate to one invention or to a single inventive concept, a priori.

Both inventive concepts could be searched without additional effort

4. Consequently, this opinion has been established in respect of the following parts of the international application:

all parts
 the parts relating to claims Nos.

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Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | |
|-------------------------------|----------------|-----|
| Novelty (N) | Claims | YES |
| | Claims 1-13,15 | NO |
| Inventive step (IS) | Claims | YES |
| | Claims 1-13,15 | NO |
| Industrial applicability (IA) | Claims 1-13,15 | YES |
| | Claims | NO |

2. Citations and explanations:

The following documents identified in the International Search Report have been considered for the purposes of this report:

- D1 SU726692 ✓
- D2 US4706683 ✓
- D3 JP2000325481 ✓
- D4 RU2186597 ✓
- D5 EP 1245250 ✓
- D6 US5758642 ✓
- D7 US3982532 ✓

The present claims 1-12,15 define a device for delivering a supply of gases to a user comprising: a patient interface, in use in fluid communication with said supply of gases and supplying said gases to said user, at least one member integrated with or attached to said patient interface, wherein the boundary between said outlet member and said interface forms at least one narrow outlet vent that in use passes a substantial portion of the expired gases of said user.

The present claim 13 defines a device for delivering a supply of gases to a user comprising: a patient interface, in use in fluid communication with said supply of gases and supplying said gases to said user, said patient interface including a hollow body and a cushion where said cushion extends below said user's chin.

NOVELTY AND INVENTIVE STEP: Claims 1-12,15

D1 discloses a protecting mask which has a body with a part restricting the space under that mask. The upper part of the mask has air conducting channels to connect with the source of air, and the lower part of the mask has a hole to allow the gases to escape the mask. "The protecting mask" is a device for delivering a supply of gases to a user, "the upper part of the mask" is a patient interface, in use in fluid communication with said supply of gases and supplying said gases to said user, at least one member integrated with or attached to said patient interface, "the hole in the lower part of the mask" is a narrow outlet vent that in use passes a substantial portion of the expired gases of said user located in the boundary between said outlet member and said interface forms (column 1, lines 14-21 with reference to SU584611). In addition to that D1 discloses (Fig. 1,2, column 2 line 5 – column 3 line 40) a mask, which is a device for delivering a supply of gases to a user comprising: a patient interface (1), in use in fluid communication with said supply of gases (channels 11,12) and supplying said gases to said user, a

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Box No. VI Certain documents cited

1. Certain published documents (Rules 43bis.1 and 70.10)

Application No.

Patent No.Publication date
(day/month/year)Filing date
(day/month/year)Priority date (valid claim)
(day/month/year)

US 6736139 B1

18 May 2004

US 6736139 B1 discloses ventilation mask (12) which is a device for delivering a supply of gases to a user comprising: a patient interface, in use in fluid communication (by means of connection (32)) with supply of gases forms at least one narrow outlet vent that in use passes a substantial portion of the expired gases of said user. The narrow outlet vent is not numbered, but could be easily identified by person skilled in art at middle down part of Fig. 1 or Fig. 2. The citation does not disclose one member integrated with or attached to said patient interface which is an obvious selection. Claims 1-12,15 are not new and do not involve inventive step in view of this citations.

2. Non-written disclosures (Rules 43bis.1 and 70.9)

Kind of non-written disclosure

Date of non-written disclosure
(day/month/year)Date of written disclosure
referring to non-written disclosure
(day/month/year)

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PCT/NZ2004/000194

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: V.

at least one member integrated with or attached to said patient interface (which is not numbered in Fig.1 but could be identified as an element which is forming left border of the outlet vent (4), wherein the boundary between said outlet member and said interface forms at least one narrow outlet vent (4) that in use passes a substantial portion of the expired gases of said user. Claims 1-12,15 are not new and do not involve inventive step in view of this citation.

D2 discloses face mask (2) which is a device for delivering a supply of gases to a user comprising: a patient interface, in use in fluid communication with said supply of gases (32,14) and supplying said gases to said user, forms at least one narrow outlet vent that in use passes a substantial portion of the expired gases of said user. The narrow outlet vent is not numbered, but could be easily identified by person skilled in art at middle down part of Fig. 2. D2 does not disclose one member integrated with or attached to said patient interface which is an obvious selection. Claims 1-12,15 are not new and do not involve inventive step in view of this citations.

D3 discloses mask for respiration (20) which is a device for delivering a supply of gases to a user comprising: mask body cover (40) which is a patient interface, in use in fluid communication with said supply of gases and supplying said gases to said user by means of channel (18), circular leak ole (53) which is one narrow outlet vent that in use passes a substantial portion of the expired gases of said user {Abstract, Fig. 1,4,6}. D4 does not disclose at least one member integrated with or attached to said patient interface, wherein the boundary between said outlet member and said interface forms but it is an obvious selection. Claims 1-12,15 are not new and do not involve inventive step in view of this citation.

NOVELTY AND INVENTIVE STEP: Claim 13

D1 discloses a mask which is device for delivering a supply of gases to a user. D1 discloses a patient interface, in use in fluid communication with said supply of gases and supply said gases to said user. D1 discloses patient interface including a hollow body and a special air channel 5 which is located under the chin an which is a cushion where said cushion extends below said user's chin {AbstractFig. 1,2, column 2 line 5 – column 3 line 40}. Claim 13 is not new and do not involve inventive step in view of this document.

D4 discloses semimask for respirator which is a device for delivering a supply of gases to a user. D4 discloses portion of semimask which is made in the form of four conjugated arcs which is a patient interface, in use in fluid communication with said supply of gases and supply said gases to said user. D4 discloses chin portion of semimask is formed as arc of circle extending inside hemisphere and conjugated with vertical arcs of circle of front part adjoining to cheeks which is said patient interface including a hollow body. D4 discloses a chin part of obturator which is a cushion where said cushion extends below said user's chin {Abstract, Fig. 1-3, page 3 column 2 line 56 – page 6 column 2 line 17}. Claim 13 is not new and do not involve inventive step in view of this document.

D5 discloses a medical or flight crew mask which is a device for delivering a supply of gases to a user comprising: a patient interface, in use in fluid communication with said supply of gases and supply said gases to said user. D5 discloses breathing cavity (16) which is a hollow body. D5 discloses under chin wall (18) which is a cushion where said cushion extends below said user's chin {Entire document}. Claim 13 is not new and do not involve inventive step in view of this document.

D6 discloses a face mask which is a device for delivering a supply of gases to a user comprising: a patient interface, in use in fluid communication with said supply of gases and supply said gases to said user. D6 discloses body portion forming an open sided chamber having a peripheral edge for contacting the face of the patient which is said patient interface including a hollow body. D6 discloses a chin portion with peripheral wall is configured to contact a forward portion of the chin of the patient which is a cushion where said cushion extends below said user's chin {entire document}. Claim 13 is not new and do not involve inventive step in view of this document.

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

continuation of: V

D7 discloses a breathing mask which is a device for delivering a supply of gases to a user comprising: a patient interface, in use in fluid communication with said supply of gases and supply said gases to said user. D7 discloses said patient interface including a hollow body. D7 discloses a rigid arc-shaped portion to be pressed against the chin which is a cushion where said cushion extends below said user's chin {Entire document}. Claim 13 is not new and do not involve inventive step in view of this document.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

| | | |
|--|--|---|
| Applicant's or agent's file reference: 504319 NJC | FOR FURTHER ACTION | see Form PCT/ISA/220 as well as, where applicable, item 5 below. |
| International application No. PCT/NZ2004/000194 | International filing date (day/month/year) 20 August 2004 | (Earliest) Priority Date (day/month/year) 3 September 2003 |
| Applicant FISHER & PAYKEL HEALTHCARE LIMITED (ET AL.) | | |

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 7 sheets.

It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

The international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see Box No. I.

Certain claims were found unsearchable (See Box No. II).

Unity of invention is lacking (See Box No. III).

4. With regard to the title,

the text is approved as submitted by the applicant.

the text has been established by this Authority to read as follows:

5. With regard to the abstract,

the text is approved as submitted by the applicant.

the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the drawings,

a. the figure of the drawings to be published with the abstract is Figure No. 3

as suggested by the applicant.

as selected by this Authority, because the applicant failed to suggest a figure.

as selected by this Authority, because this figure better characterizes the invention.

b. none of the figures is to be published with the abstract.

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Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely:
2. Claims Nos.: 14 because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically: This claim is considered to define two inventive concepts within a single claim. It is considered too unclear for a meaningful search to be performed.
3. Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

See extra sheet

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/NZ2004/000194

plemental Box

(be used when the space in any of Boxes I to VIII is not sufficient)

ntinuation of Box No: III

claims do not relate to one invention only (or to a group of inventions so linked as to form a single general inventive concept). In assessing whether there is more than one invention claimed, I have given consideration to those features which can be considered to be "special technical features". These are features that potentially distinguish the claimed combination of features from the prior art. Where different claims have different special technical features they define different inventions. I have found claims having different special technical features as follows:

- (1) Claims 1-12. It is considered that "one narrow outlet vent" comprises a first special technical feature.
- (2) Claims 13. It is considered that "hollow body and a cushion where said cushion extends below said user's chin" comprises a second special technical feature.

Since these groups of claims do not share any of the special technical features identified, a technical relationship between the inventions does not exist. Accordingly the claims do not relate to one invention or to a single inventive concept, a priori.

Both inventive concepts could be searched without additional effort

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Box No. IV Text of the Abstract (Continuation of item 5 of the first sheet)

A mask (30) is disclosed that has a gas outlet (37) which is quiet and provides for a diffused outlet flow of gases. The outlet (37) is preferably a slot formed between a hollow body and cover over said hollow body. The mask also preferably extends and seals under a users chin in use.

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A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl. 7: A61M 16/06 A62B 18/02

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

SEE ELECTRONIC DATABASES CONSULTED

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
DWPI: A61M-016, A62B, mask, outlet, exhaust, aperture, hole, port, slot, slit, narrow, thin, slender, split, constrict, taper, wide, broad, long, chin, jaw.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|-----------|---|-----------------------|
| X | SU 726692 A (KUBANSK SELSKOKHOZYAST INST (SU)) 7 September 1978 Abstract, Fig. 1,2, column 1 lines 14-21, column 2 line 5 – column 3 line 40 | 1-13,15 |
| X | US 4706683 A (CHILTON ET AL.) 17 November 1987 Fig 2,3 | 1-12,15 |
| X | JP 2000325481 A (FUJISAWA PHARMACEUT CO LTD) 28 November 2000 Abstract, Fig. | 1-12,15 |
| P,X | US 6736139 B1 (WIX) 18 May 2004-10-26 Fig. 1,2 | 1-12,15 |

 Further documents are listed in the continuation of Box C See patent family annex

| | |
|---|--|
| Special categories of cited documents: | |
| "A" document defining the general state of the art which is not considered to be of particular relevance | "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention |
| "E" earlier application or patent but published on or after the international filing date | "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone |
| "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) | "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art |
| "O" document referring to an oral disclosure, use, exhibition or other means | "&" document member of the same patent family |
| "P" document published prior to the international filing date but later than the priority date claimed | |

Date of the actual completion of the international search
26 October 2004

Date of mailing of the international search report

5 NOV 2004

Name and mailing address of the ISA/AU
AUSTRALIAN PATENT OFFICE
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E-mail address: pct@ipaaustralia.gov.au
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MATTHEW FORWARD
Telephone No : (02) 6283 2606

INTERNATIONAL SEARCH REPORT

International application No.

PCT/NZ2004/000194

C (Continuation).

DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|-----------|---|-----------------------|
| X | RU 2186597 C1 (SORBENT INTRODUCTION CENTRE STOCK CO) 10 August 2002 Abstract, Fig. 1-3, page 3 column 2 line 56 – page 6 column 2 line 17. | 13 |
| X | EP 1245250 A2 (ROSEMOUNT AEROSPACE INC.) 2 October 2002 Entire document | 13 |
| X | US 5758642 A (CHOI) 2 June 1998 Entire document | 13 |
| X | US 3982532 A (HALLDIN ET AL.) 28 September 1976 Entire document | 13 |

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/NZ2004/000194

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

| Patent Document Cited in Search Report | | Patent Family Member | | | | | |
|---|------------|---|--|---|--|--|--|
| SU | 726692 | NONE | | | | | |
| US | 4706683 | NONE | | | | | |
| JP | 2000325481 | NONE | | | | | |
| US | 6736139 | NONE | | | | | |
| RU | 2186597 | NONE | | | | | |
| EP | 1245250 | US 2002139368 | | | | | |
| US | 5758642 | NONE | | | | | |
| US | 3982532 | AT 1010774 CH 580428 FI 366674 JP 50106496 | BE 823499 DE 2459651 FR 2255084 NO 744562 | CA 1014816 DK 660274 GB 1494330 SE 7317152 | | | |

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

END OF ANNEX

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